IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF ALABAMA

CAROLYN ROLLINS and LESTER ROLLINS,	)	
Plaintiffs,	)	
vs.	)	**CASE No: 2:05cv00452-MHT-SRW**
BAYER CORPORATION,	)	**DEMAND FOR JURY TRIAL**
Defendant.	)	

A M E N D M E N T
T O
C O M P L A I N T

COME NOW the Plaintiffs, by and through their undersigned counsel, and amend their original complaint against Bayer Corporation as follows:

JURISDICTION

1. The jurisdiction of this Court is founded upon diversity of citizenship, 28 U.S.C. Sec. 1332, with there being complete diversity of citizenship between the Plaintiffs and Defendants, and with an amount in controversy for each Plaintiff, individually, in excess of Seventy-Five Thousand Dollars ($75,000.00), exclusive of interest and costs.

PARTIES

2. Plaintiff Carolyn Rollins is over the age of nineteen years and is a resident citizen of Montgomery, Montgomery County, Alabama.

3. Plaintiff Lester Rollins is over the age of nineteen years and is a resident citizen of Montgomery, Montgomery County, Alabama. Lester Rollins is, and was at all times relevant hereto, the spouse of Carolyn Rollins.

4. Defendant Bayer Corporation is a corporation of the state of Indiana, with its principal place of business in Pittsburgh, Pennsylvania. At all relevant times herein, Bayer Corporation was in the business of promoting, manufacturing and distributing products containing Phenylpropanolamine ("PPA"). Defendant does business in Alabama and at all relevant times hereto, marketed, promoted, warranted and sold it products containing PPA in Alabama and throughout the United States.

FACTUAL ALLEGATIONS

5. At all times material to this action, Defendant engaged in the designing, testing, manufacturing, marketing, advertising, distributing and selling of non-prescription, pharmaceutical products, including cold remedy products containing Phenylpropanolamine or PPA. Defendant Bayer Corporation designed, tested, manufactured, marketed, advertised, distributed and/or sold Alka Seltzer Plus Cold Medicine, which contained PPA.

6. PPA is a sympathomimetic amine similar in structure and function to amphetamine and ephedrine. It also has a direct vasoconstricting effect on the human body. A sympathomimetic drug such as PPA increases arterial blood pressure, produces pupillary dilatation, salivation and lacrimation, inhibits gut motility, and inhibits the urinary bladder.

7. For decades, the scientific and medical communities have known that human consumption of sympathomimetic drugs can cause serious, life threatening adverse health effects including damage to the cardiovascular and neurological systems. Known effects associated with the use of PPA include hypertension, myocardial injury, headache, hypertensive encephalopathy, agitation, psychosis, hemorrhagic and ischemic cerebrovascular incidents, atrial and ventricular brady- and tachydysrhythmias, cardiopulmonary arrest, seizures, bowel ischemia

and infarction and cerebral arteritis. Defendant, as a manufacturer of pharmaceutical products, knew of the dangers associated with the consumption of sympathomimetic drugs and as such was fully aware of the dangers posed by the consumption of PPA. Despite this knowledge, for years, Defendant used PPA in its non-prescription over-the-counter cold medications, including Alka Seltzer Plus Cold Medicine. Defendant marketed and advertised its products to the general public and to the medical community as being safe and effective for its stated purposes.

PPA'S FDA HISTORY

8. PPA was first synthesized in 1910 and was used in the early 1930s as an alternative to ephedrine in maintaining blood pressure after surgery. The ability of PPA to raise arterial blood pressure is primarily due to the action of PPA on constricting blood vessels via direct and, possibly, indirect activation of alpha-1-adrenoceptors.

9. PPA in the United States has been used in two primary over-the-counter ("OTC") markets: as a decongestant in cough and cold products and as an appetite suppressant in diet pills. PPA was first used as a decongestant in 1936 and produces vasoconstriction of the mucosal blood vessels to alleviate congestion. PPA was first used as an appetite suppressant in 1972 for weight loss.

10. In 1938, the Food and Drug Administration ("FDA") was created as part of the enactment of the Federal Food, Drug and Cosmetic Act of 1938 (the "Act"), 52 Stat. 1040 (codified as amended at 21 U.S.C. §§ 301 et seq. (2000)). Under the Act, new drugs required the approval of the FDA. Existing drugs were "grandfathered" under the Act and thus exempted from the testing requirements of new drugs. No proof of safety was required for grandfathered

drugs. Having been on the market as a decongestant since 1936, PPA was exempt from the new drug approval process.

11. In 1962, the Drug Amendments to the Act, Pub. L. No. 87-781, 76 Stat. 780, required proof of effectiveness for all new drugs, including those approved between 1938 and 1962. The pre-1938 drugs previously "grandfathered" under the Act, such as PPA, continued their exempt status.

12. The FDA regulates all OTC drugs, which are classified by the FDA as Category I (safe and effective); Category II (not safe and effective); or Category III (insufficient data to assess safety).

13. In 1972, the FDA began to review OTC drugs for classification. As an OTC product marketed before 1972, PPA was allowed to continue on the market until a "final monograph" relating to the drug's category became effective. The FDA never finalized a monograph for PPA because of concerns about reports of hemorrhagic stroke associated with using this drug. PPA was never classified by the FDA as a Category I (safe and effective) OTC drug.

14. In 1999, more than 4.5 Billion doses of PPA were sold in products such as Alka Seltzer Plus Cold Medicine.

PPA'S ASSOCIATION WITH RISK OF HEMORRHAGIC STROKE

15. For more than twenty years, the OTC pharmaceutical industry, including the Defendant, has been aware of reports of hemorrhagic stroke associated with the use of PPA. Furthermore, published reports of PPA use associated with hypertension (increased blood pressure) date back over thirty years. See Humberstone (1969) and Cuthbert (1969).

16. Since 1979, there have been over 30 published case reports in the respected medical literature of stroke and PPA ingestion, often after the "first use" of the product. A number of these authors, medical authorities and medical "Watch-Dog" agencies such as Public Citizen called for the removal of PPA from the OTC market. Case reports and medical literature reviews of stroke after PPA exposure appearing in the scientific and medical literature include but are not limited to:

- King (1979)
- Elliot and White (1981)
- Bernstein and Diskant (1982)
- Johnson, Etter, and Reeves (1983)
- Mueller (1983)
- Pentel (1984)
- Fallis and Fisher (1985)
- Jackson (1985)
- Kikta (1985)
- McDowell (1985)
- Stoessl (1985)
- Edwards (1987)
- Glick (1987)
- Kase (1987)
- Forman (1989)
- Montalban (1989)
- Barinagarrementeria, Mendez, et al. (1990)
- Chung (1998)
- Hamilton (2000)
- Lake (2000)

17. In 1979, an article in the *Medical Journal of Australia* noted a case of hypertension and cerebral hemorrhage after PPA product use.

18. In the mid-1980s, a study by O'Neill and Van de Carr (FDA report, 1984; cited in Tsong, 2000) postulated a relationship between PPA ingestion and hemorrhagic stroke.

19. In 1981, an editorial in the *American Journal of Medicine* and the consumer group

Public Citizen expressly recommended against PPA use in the OTC market because of safety risks, especially those related to hemorrhagic stroke.

20. In 1983, the FDA determined that PPA raises blood pressure and later met with industry officials to discuss the need for more data to evaluate the safety concerns surrounding PPA and life threatening adverse reactions including hypertension and stroke.

21. In 1984, the FDA banned the sale of products containing a combination of PPA and caffeine due to safety and health concerns.

22. In 1985, the FDA issued a tentative final monograph for classifying OTC nasal decongestants. PPA, however, was omitted from the monograph due to safety concerns.

23. In 1990, a review article of 142 PPA case reports concluded that the most serious adverse reactions (stroke and seizure) were caused by PPA products.

24. Also, in 1990, a subcommittee of the U.S. House of Representatives Small Business Committee held hearings on diet drugs containing PPA. At the hearings, several scientific witnesses and one national society of physicians called for the removal of PPA from the OTC market because of safety and health concerns. After the hearings, the subcommittee's chairman, U.S. Representative Ron Wyden, wrote to the FDA expressing his concern about PPA and noting that an epidemiological study had demonstrated that PPA preparations lead all other OTC products in the number of serious and fatal adverse effects in people under 29 years of age, as well as the number of contacts with Poison Control Centers each year.

25. Between 1969 and 1991, 29 cases of cerebro-vascular incidents associated with PPA use were reported to the FDA through its spontaneous adverse event reporting system. Of these 29 reports, 22 were hemorrhagic strokes associated with PPA use (16 appetite suppressant

cases and 6 "cold and cough" cases). Of these strokes, 55% occurred after just one dose of the PPA product.

26. In 1991, H. M. Jolson produced an internal report for the FDA that examined the reports of cerebro-vascular stroke in the FDA spontaneous reporting system for PPA versus all other drugs for women for the period of 1969-1991. Her analysis indicated that cerebro-vascular stroke was the most common event for PPA-containing products; that such events were also evident in cough-cold preparations; and that such events were often associated with first use of PPA products. Still, consumers were not being timely or adequately warned by the pharmaceutical industry about the then-known association between PPA and stroke.

27. In 1991, the FDA held a public meeting to address the issues regarding safety and effectiveness of PPA before publishing a final monograph for the drug. Reports of hemorrhagic stroke associated with PPA use were raised at the meeting.

28. Between 1991 and 2000, the FDA received an additional 22 reports of hemorrhagic strokes associated with PPA use (19 "cold and cough" cases, 3 appetite suppressant cases). Four of these consumers had died from their stroke injuries.

29. Thus, by the time Carolyn Rollins ingested Alka Seltzer Plus Cold Medicine in May 1996, numerous reports of PPA-related hemorrhagic stroke had been made to the FDA and knowledge of that information and the reasons why PPA should be removed from the marketplace were well known, or should have been, to the Defendant. These numerous adverse reports and the ongoing Yale Study, infra, were known, or should have been known, to the Defendant, however, said Defendant persisted in the distribution, marketing and sale of Alka Seltzer Plus Cold Medicine and other PPA-laden products.

THE YALE HEMORRHAGIC STROKE STUDY

30. In March of 1993, the FDA issued a letter to the Nonprescription Drug Manufacturers Association outlining its concerns regarding the safety of PPA and informed industry that it intended to classify PPA as a Category III drug (insufficient data to assess safety). To avoid this classification, manufacturers of PPA proposed a study, which later became known as the Yale Hemorrhagic Stroke Study (or "Yale Study"), to investigate the link between PPA and strokes. While the study was ongoing, the manufacturers were able to continue selling PPA products.

31. In a December 13, 2000, *New York Times* article the FDA director of OTC drugs stated that if the Yale study had not been undertaken, "The agency probably would have decided to take PPA off the market [in 1992]."

32. The FDA began working with manufacturers of PPA and investigators at Yale University School of Medicine to design the protocol for the Yale Study, a case-control epidemiological study to examine and quantify the risk of hemorrhagic stroke and PPA use.

33. The Yale Study, which was funded by the pharmaceutical industry, began in September 1994. It involved 702 patients and 1376 control subjects and was completed in June of 1999.

34. The Yale Study confirmed by epidemiological methodologies that the use of PPA substantially increases the risk of hemorrhagic stroke. Use of PPA in an appetite suppressant was significantly associated with the risk of hemorrhagic stroke (odds ratio of 16.58). The "first use" of any PPA product involving "cough/cold" remedies was also associated with the risk of hemorrhagic stroke (odds ratio of 3.13).

35. Defendant was provided with the final results of the Yale Study, at the latest, during the May 2000 meetings with the FDA, but was also aware of the existence of that ongoing epidemiological study for years prior to that date and the concerns that existed in the medical/scientific community that PPA was associated with causing hemorrhagic strokes in human beings.

36. On November 6, 2000, the summary results of the Yale Study appeared in the popular press, including the front page of the *New York Times* newspaper. On December 21, 2000, the study and its results were officially published as an original, lead article in the peer-reviewed *New England Journal of Medicine*. Its authors concluded that the Yale Study, **"provides strong epidemiological evidence of the association between the use of phenylpropanolamine and the risk of hemorrhagic stroke**." Walter N. Kernan et al., Phenylpropanolamine and the Risk of Hemorrhagic Stroke, 343 New Eng. J. Med. 1826, 1831 (2000).

37. Read in conjunction with the large body of prior published medical case reports, FDA adverse event reports and related clinical observations, the Yale Study establishes by every conventional legal criteria and standard the "general causation" principle: PPA causes hemorrhagic strokes in human beings.

THE FDA RECOMMENDS PPA BE WITHDRAWN FROM THE MARKET

38. On October 19, 2000, members of the Non-Prescription Drugs Advisory Committee for the FDA's Center for Drug Evaluation and Research met to vote, in an advisory capacity, on the safety of PPA in light of the Yale Study findings. The 15-member panel voted overwhelmingly (13 in favor) that PPA was unsafe, and recommended to the FDA the removal

of PPA from the marketplace.

39. On November 6, 2000, the FDA, in reliance upon its advisory committee and the findings of the Yale Study, officially recommended that all makers of OTC pharmaceuticals that contain PPA voluntarily remove this chemical from their products. By correspondence of the same date, the FDA urged all manufacturers and sellers of OTC products containing PPA to cease immediately the distribution and sale of said products.

40. On the same day, the FDA's Nonprescription Drugs Advisory Committee issued the following advisory:

Food and Drug Administration
Public Health Advisory
Subject: Safety of Phenylpropanolamine
November 6, 2000

The Food and Drug Administration (FDA) is issuing a public health advisory concerning phenylpropanolamine hydrochloride. This drug is widely used as a nasal decongestant (in over-the-counter and prescription drug products) and for weight control (in over-the-counter drug products). FDA is taking steps to remove phenylpropanolamine from all drug products and has requested that all drug companies discontinue marketing products containing phenylpropanolamine.

Phenylpropanolamine has been marketed for many years. A recent study reported that taking phenylpropanolamine increases the risk of hemorrhagic stroke (bleeding into the brain or into tissue surrounding the brain) in women. Men may also be at risk. Although the risk of hemorrhagic stroke is very low, FDA recommends that consumers not use any products that contain phenylpropanolamine.

FDA's Nonprescription Drugs Advisory Committee (NDAC) recently discussed this study and other information on phenylpropanolamine. NDAC determined that there is an association between phenylpropanolamine and hemorrhagic stroke and recommended that phenylpropanolamine not be considered safe for over-the-counter use.

Although this risk of hemorrhagic stroke is very low, FDA has significant concerns because of the seriousness of a stroke and the inability to predict

> *who is at risk. FDA does not consider the conditions for which phenylpropanolamine is used (over-the-counter or by prescription) as justifying the risk of this serious event. Other products are available for use.*
>
> *In the meantime, consumers can identify over-the-counter cough-cold, nasal decongestant, and weight control products containing this ingredient by looking for "phenylpropanolamine" in the list of active ingredients on the label. Consumers can check with their health care provider or pharmacist to see whether their prescription cough-cold or nasal decongestant product contains phenylpropanolamine. We advise consumers to discuss alternative over-the-counter and prescription products with their health care providers or pharmacists.*

41. FDA analysts, relying upon the Yale Study, estimate that 200-500 strokes occur per year in United States women age 18-49 resulting from ingestion of PPA products.

42. The FDA has concluded after internal and independent analysis that the Yale Study was "carefully designed," "conducted with great attention to detail," and constitutes a "careful analysis." Moreover, the FDA has confirmed the major findings of the Yale Study by conducting its own analysis of the epidemiological data. The FDA has concluded that the Yale Study "strongly supports" their working hypothesis: PPA use increases the risk of hemorrhagic stroke. Indeed, the FDA has concluded that the Yale Study results largely fulfill the criteria needed to establish "causality."

DEFENDANT'S KNOWLEDGE ABOUT PPA AND THE RISK OF STROKE

43. Bayer Corporation knew or should have known, about the published decades long history of case reports in the published medical literature establishing a meaningful clinical/medical association between PPA and risk of hemorrhagic stroke, as well as from the fifty-plus adverse event reports filed with the FDA, as well as numerous adverse reports from the

Company's own internal safety surveillance database all of which related to hemorrhagic strokes arising from PPA exposure.

44. Bayer Corporation also was and is fully aware of the significant underreporting of adverse events associated with OTC drugs in spontaneous safety surveillance systems such as that at the FDA regarding PPA and hemorrhagic strokes. The FDA has estimated that as few as 1% of all PPA-associated adverse events have been reported. Utilizing that learned estimate, the 44 FDA adverse reports between 1969 and 2000 which arose from cases of hemorrhagic stroke associated with PPA use would translate into 4400 such cases over the years in question.

45. Defendant used PPA in its products due to its efficacy as a vasoconstrictor. PPA works to constrict blood vessels in congested nasal mucosa thereby relieving swelling and congestion and other symptoms associated with cold, flu and sinus ailments. However, PPA is not selective of nasal mucosa, but also constricts blood vessels in other parts of the body including the brain and heart. The process of constricting blood vessels raises blood pressure and causes hypertension. When blood pressure is raised to a critical level it increases the likelihood of severe life threatening and often fatal effects including but not limited to heart attack and stroke.

46. Defendant was aware or should have been aware of the evidence relating PPA to potentially life threatening and fatal reactions.

47. In addition to studies conducted by the FDA and the scientific community, Defendant, separately and through trade organizations, has engaged in collecting data and information tending to demonstrate the connection between PPA and serious adverse health affects.

48. At all times material, Defendant was a member of the Consumer Healthcare Products Association ("CHPA") (f/k/a Non-Prescription Drug Manufacturers Association ("NDMA")). A function of the CHPA is to provide information to its members concerning issues of importance to the industry. As a member of the CHPA, Defendant participated in numerous communications and discussions directly related to the safety and known adverse health effects of products containing PPA.

49. In fact, the CHPA (then known as NDMA) set up a PPA Task Force whose objective was, among other things, to study the adverse effects of PPA and to address concerns of the scientific and medical communities with respect to PPA. In working to fulfill its mission, the CHPA, PPA Task Force collected information from the medical and scientific communities. Defendant, by and through the CHPA and the PPA Task Force, reviewed the collected medical and scientific literature regarding products containing PPA. As such, Defendant was fully aware of the numerous articles, treatises, reports and other evidence relating to the association between PPA and adverse health effects including hemorrhagic stroke, heart attack, arrhythmias and death.

50. Despite Defendant's knowledge concerning the adverse affects of PPA, Defendant continued to manufacture, market, advertise, distribute, and sell products containing PPA. Defendant promoted PPA products as safe and effective with little or no side effects. In addition, Defendant made no efforts to warn the general public of the dangers associated with PPA nor did Defendant take any steps to alert the medical community and inform them of the significant risks associated with PPA.

51. To the contrary, Defendant actively engaged in downplaying and minimizing any

potential adverse side effects associated with the consumption of PPA. Defendant represented to the general public and to the medical community that PPA products were safe for human consumption. Defendant concealed from the general public that PPA in OTC products could cause stroke, heart attack, heart arrhythmias and death.

52. Defendant knew or should have known that the general public considered over-the-counter medications, like Alka Seltzer Plus Cold Medicine, to be innocuous because of their ready availability without a prescription. The conception of the public relating to the safety of such over-the-counter drugs only increased the likelihood of serious adverse health consequences associated with the consumption of PPA.

53. Defendant failed to sufficiently test PPA products prior to marketing and selling them to the general public. The tests and studies performed by Defendant on PPA products lacked validity in that Defendant failed to test PPA products and their effects on the cardiovascular and central nervous systems over a reasonable period of time before and during the distribution and sale of the PPA products to the public. Nevertheless, Defendant represented PPA products as pharmaceutically tested and safe for consumption, placing the general population at risk of severe adverse health effects including hemorrhagic stoke, heart attack, heart arrhythmias and death.

54. Based upon Defendant's marketing, advertising, promotion and representation of products containing PPA as being safe and effective, Carolyn Rollins purchased and ingested Defendant's product containing PPA. However, Defendant's product was not safe as marketed, advertised, promoted and represented by Defendant in that Defendant knew or should have known that PPA products could cause hemorrhagic stroke, heart attack, heart arrhythmias and

death. Defendant failed to warn Carolyn Rollins of the dangers associated with ingesting drugs that contained PPA resulting in a stroke.

55. In May of 1996, Carolyn Rollins ingested Alka Seltzer Plus Cold Medicine as recommended. On or about May 29, 1996, following her ingestion of the medication containing PPA, Carolyn Rollins was diagnosed as having a ruptured berry aneurysm of the right internal carotid artery.

56. Throughout the time period that Defendant manufactured, offered, distributed, marketed and sold products containing PPA, it has been aware of the health risk and adverse effects of PPA. Defendant has concealed this information from Carolyn Rollins and from the general public. Plaintiff did not discover and could not have discovered this information absent Defendant's disclosure. Because of the intentional conduct of the Defendant and the pharmaceutical industry to conceal important information about the dangerous risks of PPA medications to cause hemorrhagic stroke, the information was not known to Carolyn Rollins, and in fact is still not fully known by the Plaintiff. Plaintiff has just now learned of some of these risks.

COUNT ONE
ALABAMA EXTENDED MANUFACTURER'S LIABILITY DOCTRINE

57. Plaintiff restates each and every preceding allegation of this Complaint and incorporates each by reference as though set forth in full herein.

58. At all times material hereto, the Defendant has engaged in the business of selling, distributing, supplying, manufacturing, marketing and promoting Alka Seltzer Plus Cold Medicine, a cold remedy, which contained PPA, an ingredient that is defective and unreasonably

dangerous.

59. At all times material hereto, Alka Seltzer Plus Cold Medicine was sold, distributed, supplied, manufactured and/or promoted by the Defendant and was expected to reach, and did reach, consumers, including Carolyn Rollins, without substantial change in the condition in which it left the possession of Defendant.

60. At all times material hereto, the PPA product, Alka Seltzer Plus Cold Medicine, was defective and unreasonably dangerous because:

a. When placed in the stream of commerce, the medication contained unreasonably dangerous design defects and were not reasonably safe as intended to be used, subjecting Carolyn Rollins to risks which exceeded the benefits of the drug;

b. When placed in the stream of commerce, the medication was defective in design and formulation, making use of the drug more dangerous than an ordinary consumer would expect and more dangerous than other risks associated with nasal congestion and cold symptoms;

c. The medication was insufficiently and inadequately tested;

d. The medication was not accompanied by adequate instructions and warnings to fully apprise the user of the full nature and extent of the risks and dangerous side effects associated with its use;

e. The medication increased the risk of hypertension and hemorrhagic stroke.

61. At the time of the design, manufacture, distribution and sale of this PPA medication, Defendant had knowledge of and had available to it, a safer design and ingredient for use in its medication, and failed to use the safer ingredient.

62. As a direct and proximate result of the dangerously defective condition of the drug, Carolyn Rollins sustained a ruptured berry aneurysm of the right internal carotid artery.

WHEREFORE, Plaintiff demands judgment against Defendant Bayer Corporation for

damages in an amount to be determined by a jury, as well as all costs of this action.

COUNT TWO
FAILURE TO WARN

63. Plaintiff restates each and every preceding allegation of this Complaint and incorporates each by reference as though set forth in full herein.

64. Alka Seltzer Plus Cold Medicine was defective and unreasonably dangerous when this product left the possession of the Defendant in that it contained warnings insufficient to alert Carolyn Rollins to the dangerous risks and reactions associated with the drug, including, but not limited to hemorrhagic stroke and death.

65. Carolyn Rollins used the drug for its intended purpose.

66. Carolyn Rollins could not have discovered any defect in the drug products through the exercise of reasonable care.

67. Defendant, as a manufacturer of pharmaceutical drugs, is held to the level of knowledge of an expert in the field, and further, Defendant had knowledge of the dangerous risks and side effects of the medication.

68. Carolyn Rollins did not have the same knowledge as Defendant and no adequate warning was communicated to her.

69. Defendant had a continuing duty to warn consumers of its products, including Carolyn Rollins, of the dangers associated with the medicines, and by negligently and/or wantonly failing to adequately warn of the danger associated with the use of the PPA product in question, Defendant breached its duty.

70. As a direct and proximate result of the Defendant's failure to warn, Carolyn

Rollins sustained serious and permanent injuries.

WHEREFORE, Plaintiff demands judgment against Defendant Bayer Corporation for damages in an amount to be determined by a jury, as well as all costs of this action.

COUNT THREE
BREACH OF WARRANTY OF MERCHANTABILITY

71. Plaintiff restates each and every preceding allegation of this Complaint and incorporates each by reference as though set forth in full herein.

72. When Defendant placed Alka Seltzer Plus Cold Medicine into the stream of commerce, it knew of the use for which the drug was intended, and expressly and impliedly warranted to Carolyn Rollins that use of the medicine was a safe and acceptable means of relieving nasal congestion and cold symptoms.

73. Carolyn Rollins reasonably relied upon the expertise, skill, judgment and knowledge of the Defendant and upon the express and/or implied warranty that Alka Seltzer Plus Cold Medicine was of merchantable quality and fit for use as a cold remedy.

74. Alka Seltzer Plus Cold Medicine was not of merchantable quality and was not safe or fit for its intended use because it was, and continues to be, unreasonably dangerous and unfit for the ordinary purposes for which it is used, in that it caused injury to Carolyn Rollins. The medication breached these warranties because it was unduly dangerous in expected use and did cause undue injury to Carolyn Rollins.

75. As a direct and proximate result of the Defendant's breach of these warranties, Carolyn Rollins sustained serious and permanent injuries.

WHEREFORE, Plaintiff demands judgment against Defendant Bayer Corporation for

damages in an amount to be determined by a jury, as well as all costs of this action.

COUNT FOUR
NEGLIGENCE

76. Plaintiff restates each and every preceding allegation of this Complaint and incorporates each by reference as though set forth in full herein.

77. Defendant, directly or indirectly, negligently manufactured, designed, tested, labeled, packaged, distributed, promoted, marketed, advertised, and sold, in the state of Alabama, Alka Seltzer Plus Cold Medicine, containing the drug PPA.

78. At all times material hereto, Defendant had a duty to Carolyn Rollins to exercise reasonable care in the design, manufacture, testing, processing, advertising, marketing, labeling, packaging, distribution, promotion and sale of its products containing PPA.

79. Defendant breached its duty and was negligent in its actions, misrepresentations, and omissions toward Carolyn Rollins in the following ways:

a. Failed to include adequate warnings with the medication that would alert Carolyn Rollins and other consumers to the potential risks and serious side effects of the PPA medications;

b. Failed to adequately and properly test the PPA medications before placing them on the market;

c. Failed to conduct sufficient testing on the PPA medications which, if properly performed, would have shown that PPA had serious side effects, including, but not limited to, risk of hemorrhagic stroke;

d. Failed to adequately warn Carolyn Rollins that use of the PPA medications carried a risk of disability and death due to hemorrhagic stroke and other serious side effects;

e. Failed to provide adequate post-marketing warnings or instructions after the Defendant knew or should have known of the significant risks of stroke from the use of PPA medications;

f. Failed to adequately warn Carolyn Rollins that Alka Seltzer Plus Cold Medicine should not be used in conjunction with other medicines containing PPA or other stimulants such as caffeine.

80. Defendant knew or should have known that PPA medications caused unreasonably dangerous risks and serious side effects of which Carolyn Rollins would not be aware. Defendant nevertheless advertised, marketed, sold and distributed the drug knowing that there were safer methods and products for relief of nasal congestion and cold symptoms.

81. As a direct and proximate result of the negligence of Defendant, Carolyn Rollins sustained serious and permanent injuries.

WHEREFORE, Plaintiff demands judgment against Defendant Bayer Corporation for damages in an amount to be determined by a jury, as well as all costs of this action.

COUNT FIVE
WANTONNESS

82. Plaintiff restates each and every preceding allegation of this Complaint and incorporates each by reference as though set forth in full herein.

83. Defendant, directly or indirectly, wantonly manufactured, designed, tested, labeled, supplied, packaged, distributed, promoted, marketed, advertised, warned, failed to warn and/or sold, in the state of Alabama, Alka Seltzer Plus Cold Medicine containing PPA.

84. At all times material hereto, Defendant had a duty to Carolyn Rollins to exercise reasonable care in the design, manufacture, testing, processing, advertising, marketing, testing, labeling, assembling, packaging, distribution, promotion and sale of its products containing PPA.

85. Defendant breached its duty and was wanton in its actions, misrepresentations, and omissions toward Carolyn Rollins in the following ways:

a. Failed to include adequate warnings with the drug that would alert Carolyn Rollins and other consumers to the potential risks and serious side effects of the drug;

b. Failed to adequately and properly test the drug before placing the drug on the market;

c. Failed to conduct sufficient testing on the drug which, if properly performed, would have shown that the drug had serious side effects, including, but not limited to, risk of hemorrhagic stroke;

d. Failed to adequately warn Carolyn Rollins that use of the drug carried a risk of disability and death due to hemorrhagic stroke and other serious side effects;

e. Failed to provide adequate post-marketing warnings or instructions after the Defendant knew or should have known of the significant risks of stroke from the use of the drug;

f. Failed to adequately warn Carolyn Rollins that Alka Seltzer Plus Cold Medicine should not be used in conjunction with other medicines containing PPA or other stimulants such as caffeine.

86. Defendant knew or should have known that PPA medications caused unreasonably dangerous risks and serious side effects of which Carolyn Rollins would not be aware. Defendant nevertheless wantonly and recklessly advertised, marketed, sold and distributed the drug knowing that there were safer methods and products for the relief of nasal congestion and cold symptoms.

87. As a direct and proximate result of the wantonness and recklessness of Defendant, Carolyn Rollins sustained serious and permanent injuries.

WHEREFORE, Plaintiff demands judgment against Defendant Bayer Corporation for damages in an amount to be determined by a jury, as well as all costs of this action.

COUNT SIX
FRAUD, MISREPRESENTATION AND SUPPRESSION

88. Plaintiff restates each and every preceding allegation of this Complaint and incorporates each by reference as though set forth in full herein.

89. Defendant fraudulently, intentionally and/or negligently misrepresented to Carolyn Rollins, the FDA, and the general public, the safety and effectiveness of PPA products and/or fraudulently, intentionally and/or negligently concealed material including adverse information regarding the safety and effectiveness of PPA.

90. Defendant made misrepresentations and actively concealed adverse information at a time when the Defendant knew, or should have known, that PPA had defects, dangers, and characteristics that were other than what the Defendant had represented to the FDA, and the consuming public, including Carolyn Rollins. Specifically, the Defendant misrepresented to and/or actively concealed from Carolyn Rollins, the FDA, and the consuming public that:

a. Medications containing PPA had serious side effects such as strokes, heart attack and death;

b. There had been insufficient studies regarding the safety and efficacy of the medications;

c. The medications containing PPA, and PPA itself, were fully and adequately tested;

d. Prior studies, research, reports and/or testing had been conducted linking the use of PPA medications to serious adverse reactions, including, but not limited to, stroke, heart attack and death;

e. There was a greatly increased risk of stroke and hypertension as reported in the medical literature.

91. The misrepresentations of and/or active concealment alleged above were perpetuated directly and/or indirectly by the Defendant, and its Manufacturers Association, CHPA.

92. Defendant knew or should have known that these representations were false and made the representations with the intent or purpose that Carolyn Rollins would rely on them, leading to the use of PPA by her.

93. At the time of Defendant's fraudulent misrepresentations, Carolyn Rollins was unaware of the falsity of the statements being made by Defendant and believed them to be true. Carolyn Rollins further had no knowledge of the information concealed and/or suppressed by Defendant.

94. Carolyn Rollins justifiably relied on and/or was induced by the misrepresentations and/or active concealment by Defendant and relied on the absence of safety information which the Defendant did suppress, conceal or fail to disclose to Carolyn Rollins' detriment.

95. Defendant had a post-sale duty to warn Plaintiff and the public about the potential risks and complications associated with medications containing PPA in a timely manner.

96. The misrepresentations and active fraudulent concealment by the Defendant constitutes a continuing tort against Plaintiff and other persons who ingested these PPA medications.

97. Defendant made the misrepresentations and actively concealed information about the defects and dangers of the medications with the intention and specific desire that Carolyn Rollins and the consuming public would rely on such misrepresentations or in the absence of

information would select the drug as treatment for the relief of nasal congestion and cold symptoms.

98. As a direct and proximate result of the fraudulent acts and omissions, suppression and misrepresentations of Defendant, Carolyn Rollins suffered a ruptured berry aneurysm of the right internal carotid artery.

WHEREFORE, Plaintiff demands judgment against Defendant Bayer Corporation for damages in an amount to be determined by a jury, as well as all costs of this action.

CLAIM FOR DAMAGES

Plaintiff Carolyn Rollins has sustained injuries and damages as set out herein, and does make claim for these:

a. Reasonable and necessary health care expenses incurred in the past;

b. Reasonable and necessary health care expenses which will be incurred in the future;

c. Physical pain and suffering in the past;

d. Physical pain and suffering which will be endured in the future;

e. Mental anguish suffered in the past;

f. Mental anguish which will be endured in the future;

g. Physical disability and impairment, past and future;

h. Lost wages in the past and future loss of wage earning capacity; and

i. All other incidental and consequential damages, fees and expenses.

Plaintiff Lester Rollins has sustained the loss of companionship, services and intimacy of his spouse as a direct and proximate result of the physical and mental injuries suffered by his

spouse, Carolyn Rollins.

s/Leila H. Watson
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CERTIFICATE OF SERVICE

I hereby certify that on May 24, 2005, I electronically filed the foregoing Amendment to Complaint with the Clerk of Court using the CM/ECF system, and I hereby certify that I have mailed by United States Postal Service, properly addressed and postage prepaid, to the following:

BAYER CORPORATION
c/o The Corporation Company
2000 Interstate Park Drive, Suite 204
Montgomery, AL 36109

s/Leila H. Watson
LEILA H. WATSON (ASB-3023-S74L)
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